



State of California—Health and Human Services Agency

Department of Health Services



DIANA M. BONTÁ, R.N., Dr. P.H.
Director

GRAY DAVIS
Governor

UPDATES ON VACCINE RELATED ISSUES

The Smallpox Vaccination and Pre-Existing Heart Conditions

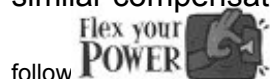
Monitoring of smallpox vaccinations given over recent months has suggested that the vaccine may cause heart inflammation (myocarditis), inflammation of the membrane covering the heart (pericarditis), and/or a combination of these two problems (myopericarditis). Heart pain (angina) and heart attack also have been reported following smallpox vaccination. The Centers for Disease Control and Prevention (CDC) has accepted a recommendation from the Advisory Committee on Immunization Practices (ACIP) that persons be excluded from the pre-event smallpox vaccination program who have known underlying heart disease, with or without symptoms, or if they have three or more known major cardiac risk factors -- hypertension, diabetes, hypercholesterolemia (high cholesterol) and smoking. CDC has distributed revised pre-vaccination clinic education materials which reflect the new exclusion criteria. For more information, please see the CDC announcement at <http://www.cdc.gov/od/oc/media/pressrel/r030331.htm>

Bifurcated Needle

The Precision bifurcated needle approved by the federal Food and Drug Administration (FDA) and provided as part of the vaccine kit does not have engineered sharps protection (i.e., it is not a "safety needle"), which is required by California regulation if such a device is available. To ensure California's readiness, the California Department of Health Services (CDHS) is beginning the State's smallpox vaccination program by vaccinating teams of public health and health care professionals using the FDA-required needle. However, CDHS and the Department of Industrial Relations (DIR) have asked FDA to actively work with medical device manufacturers to develop a high quality, effective safety needle approved for use with the smallpox vaccine. In the meantime, the California Department of Industrial Relations has clarified that the Precision bifurcated needle used to deliver the Dryvax smallpox vaccine is an approved exception.

Liability Provisions and Other Compensation

On April 11, 2003, Congress and the White House approved a smallpox vaccination compensation program to provide benefits to public health and medical response team members who are injured as a result of receiving the smallpox vaccine. It is based on a similar compensation package that is currently available to police officers and firefighters.



Do your part to help California save energy. To learn more about saving energy, visit the

www.consumerenergycenter.org/flex/index.html

Anyone permanently disabled by the vaccine would be eligible for as much as \$50,000 per year in lost wages, with no cap. Those partially disabled would be eligible for annual benefits as well, up to a lifetime maximum of \$262,000. That same amount would be available as death benefits to surviving spouses (an amount based on an existing compensation program for police and firefighters). Surviving children would get the lump payment or \$50,000 per year until they turn 18.

[Section 304 of the Federal Homeland Security Act](#) contains liability protections for those who administer smallpox vaccine under the national vaccination program. On January 24, 2003, the federal Department of Health and Human Services issued the declaration necessary to activate the Section 304 protections. The US Congress is exploring legislation to provide compensation to vaccinated individuals not covered by workers compensation and/or their family members or others who may contract vaccinia via contact with a vaccinated employee. CDHS will post additional information on this Web site as it becomes available. The unresolved liability issues are fully disclosed in the materials that public health and health care workers are asked to review prior to deciding to volunteer for the program.

Contraindications Policy and California Restrictions

California's policy regarding contraindications mirrors that of the CDC, with one additional restriction: persons with a child under one year of age in the household should not be vaccinated.

Informed and Voluntary Consent of Potential Vaccine Recipients

CDHS continues to provide as much information as possible about smallpox and the smallpox vaccine in the most organized and efficient manner possible. Potential vaccinees must have sufficient information and time to evaluate the facts, consult with their physicians, and receive any necessary medical examinations before deciding whether to volunteer for smallpox vaccination.

June 6, 2003